#10 Appeal Brief S. Bryce 10/3/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Dan ALESI et al.	)	
Serial No:	09/920,860	)	
Filed:	August 3, 2001	)	
For:	NEEDLE SAFETY DEVICE WITH TORTUOUS PATH	)	Appeal No.

APPELLANT'S BRIEF ON EX PARTE APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a brief for appealing the final rejecting of pending claims 1-3, 5-12, 14-20 and 22-26 the above-identified application.

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REAL PARTY IN INTEREST

The real party in interest for this appeal is Portex, Inc. to whom the inventors assigned the invention per an assignment recorded on August 3, 2001 with the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

As far as is known, it is believed that there are no appeals or interferences that would directly affect or be directly affected by or have a bearing on the Board's decision on the pending appeal.

STATUS OF CLAIMS

Claims 1-26 were presented for prosecution with the filing of the instant application on August 3, 2001. In response to a Restriction Requirement dated September 6, 2002, appellants elected for prosecution claims 1-3, 5-12, 14-20 and 22-26. In response to an Office Action dated November 13, 2002, an Amendment was filed on February 12, 2003 in which claim 6 was amended to overcome an objection by the examiner. An Office Action dated May 6, 2003 final rejected all of the pending claims.

The claims at issue in this case and herein on appeal accordingly are claims 1-3, 5-12, 14-20 and 22-26, as reproduced in Appendix A herein. For the convenience of the Board, withdrawn claims 4, 13 and 21 are included and noted as such in the claims of Appendix A.

STATUS OF AMENDMENTS

There was no Amendment filed subsequent to the final rejection Office Action dated May 6, 2003.

SUMMARY OF THE INVENTION

The instant invention, as set forth in claim 1, relates to an apparatus that comprises a holder (2) having one and other ends (4, 6), with the one end having an extension (8) and a sleeve (14) extending from the extension. [Page 6, lines 15-16;

Fig. 3][1] A double ended needle (18) having a base (24) is mated to the extension (8) of the holder . One end of the needle (20) extends away from the holder while the other end of the needle extends into the holder. The base (24) of the needle is substantially positioned within the sleeve (14). [Page 6, lines 6-9; Figs. 5, 6, 8] A collar (10) having a housing (12) pivotally extending therefrom is mounted about the extension (8). [Page 9, lines 3-7; Figs. 2, 5-8] A sheath (28) that has an open end is matingly fitted to the sleeve (14) to establish an environment sealed against bacteria intrusion for the one end of the needle (20). [Page 7, lines 10-20; Fig. 6] The instant invention therefore is related to the establishment of an environment for maintaining the sterility of a needle that is to be used on a patient, by providing a sheath that mates to a sleeve, which extends from an extension, or the neck, of the holder to thereby establish a sealed environment for the needle.

Additional variants of the instant invention are set forth in independent claims 10 and 18. Independent claim 10 relates to a blood drawing device which, due to the interaction of the sheath (28) fitted to the sleeve (14) that extends from the neck (8) of the holder (2), as well as the mating of the double-ended needle by means of its base (24) into the neck (8) of the holder, establishes an environment impervious to bacteria intrusion for the space inside the sheath that encloses the needle (20) that is to be used with a patient. The same disclosures as noted above with respect to claim 1 provide support for claim 10.

Independent claim 18 relates to a needle device that, similarly, by means of the interrelationship between the sheath (28) that covers needle (2), the base or needle hub (24) that is mated to the neck (8) of the body holder (2) and the sleeve (14) that extends from the neck, is able to establish an environment impervious to bacteria intrusion inside the space of the sheath (28) where the needle (20) resides.

Other aspects of the invention include the recitation of the interaction between the different surfaces (28s, 14s) of the sheath (28) and sleeve (14) that together effect a tortuous path (30) to seal the inside of the sheath against potential bacteria

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[1] The designations of the different elements recited in the claims are in parentheticals while the pages of the disclosure that provide support are bracketed.

intrusion. [Page 7, lines 12-20; Fig. 6] This aspect of the invention is set forth in dependent claims 2, 11 and 19.

Claims 3, 12 and 20 each define sleeve (14) to be integrally extending from the extension or the neck (8) of the holder. [Page 6, lines 15-16; Figs. 2 and 4-6]

Claims 5, 14 and 22 each define housing (12) to have an integral locking means (46) for grasping the needle (20) when the housing is pivoted to cover the needle after the sheath (28) has been removed from the sleeve. [Page 9, lines 3-8; Fig. 5]

The coacting locking portions provided at the collar (10) or sleeve (14), and the housing (12) is defined in claims 6, 15 and 23.

Claims 7, 16 and 26 each define the placing of a cover (16) at the end (6) of the holder (2) to provide a sterile environment for the inside 19 of the holder. [Page 6, lines 17-21; Figs. 4, 5]

In addition, claim 16, as well as claims 9 and 24 individually, each define either means or a tamper seal (40) provided on the sheath (28) and the sleeve (14) to provide evidence that there is a sealed environment (34) for the needle (20). [Page 8, lines 13-17; Fig. 2]

ISSUES

The examiner has maintained her rejection of claims 1-3, 5-8, 10-12, 14-15, 17-20, 22-23 and 25-26 under 35 U.S.C. 102(b) as being anticipated by Hollister U.S. patent 5,277,311. The examiner has moreover finally rejected claims 9, 16 and 24 under 35 U.S.C. 103(a) as being unpatentable over Hollister in view of Imbert U.S. patent 6,027,482.

In view of the examiner's rejections, the issues presented herein on appeal are the following:

1. Is the 35 U.S.C. 102(b) rejection of the above noted claims in view of Hollister justified?

2. Is the 35 U.S.C. 103(a) rejection of claims 9, 16 and 24 in view of the combination of Hollister and Imbert sustainable?

GROUPING OF CLAIMS

The being appealed claims, as discussed above in the Summary of the Invention section, are divided into three sets, namely claims 1-9, 10-17 and 18-26. Ignoring withdrawn claims 4, 13 and 21, dependent claims 2-3 and 5-9 each depend from claim 1, dependent claims 11-12 and 14-17 each depend from claim 10, and dependent claims 19-20 and 22-26 each depend from claim 18. In the hereinbelow Argument section, in addition to independent claims 1, 10 and 18, appellants will also argue separately the patentability of claims 2-3, 6-7, 9, 11-12, 15-16, 19-20, 23-24 and 26. Thus, appellants respectfully submit that all of the claims do not stand or fall together, but rather that the patentability of each of the above noted claims to which discussion is to be had hereinbelow should be considered independently.

ARGUMENT

Issue 1

Is each of claims 1-3, 5-8, 10-12, 14-15, 17-20, 22-23 and 25-26 anticipated by Hollister U.S. patent 5,277,311 under 35 U.S.C. 102(b)?

"In order to prove that a claim is anticipated under 35 U.S.C. 102(b), defendants must present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim." In re Cruciferous Sprout litigation, 301 F.3d 1343, 1348 (Fed. Cir. 2002). In In re Robertson, the CAFC also held: "Anticipation under 35 U.S.C. 102(e) requires that `each and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference`". 169 F.3d 743, 746 (Fed. Cir. 1999)

Independent claim 1 recites a holder that has an extension at its one end, and a sleeve extending from the extension. Moreover, the apparatus of claim 1 includes

a double ended needle having a base that is substantially positioned within the sleeve. Furthermore, the apparatus of claim 1 includes a sheath that matingly fits to the sleeve to establish an environment which seals the needle of the double ended needle that extends away from the holder from bacteria intrusion. Claim 10 defines a blood drawing device that has a holder which has a neck and to which a sleeve extends. The base of a double ended needle is connected to the neck of the holder. A sheath is fitted to the sleeve in such a way that the sleeve, the base and the sheath in combination establish an environment for the space inside the sheath that encloses the needle impervious to bacteria intrusion. Independent claim 18 likewise defines a needle device that has a body which has a neck to which a needle is connected by means of a base. The needle device of claim 18 has a sleeve that extends from the neck to enclose the base, and a sheath that fits to the sleeve such that the sleeve, the base and the open end of the sheath that mates to the sleeve in combination establish a bacteria free space inside the sheath where the needle extends from the base.

Hollister discloses a vacuum tube holder 2 that has mounted to its neck or receptacle end 6 a collar 18. A housing 20 is connected to a collar by way of a living hinge 24. A double ended needle assembly 30 is threadingly mated to receptacle end 6 of holder 2. See Fig. 1. There is therefore no sleeve extending from an extension/neck disclosed in Hollister.

In the Office Action, the examiner asserts that Hollister discloses a holder "having an extension (16) and a sleeve integrally extending from said extension". [Page 2 of the May 6, 2003 Office Action] Yet Hollister discloses in column 3, lines 23-28, that element 16 is a protuberance, or boss, about which collar 18, to which a housing 20 is connected, is mounted. Further, in column 3, lines 13-22, Hollister discloses that receptacle end 6 extends from holder 2; and as can clearly be seen from the figures, for example Fig. 1, the respective top end surfaces of receptacle end 6 and collar 18 are flushed with each other. Thus, if receptacle end 6 is the same as the claimed extension/neck of the instant invention, then there could not possibly be any sleeve, such as 14 shown in Fig. 4 of the specification of the instant invention, disclosed in Hollister. Moreover, as clearly shown in Fig. 4 of Hollister, the needle hub (labeled 38 in Fig. 1) of the double ended needle assembly 30 is mostly

positioned above receptacle end 6. In contrast, as defined in the independent claims of the instant invention, the base of the double ended needle is either positioned substantially within the sleeve [claims 1 and 10] or enclosed by the sleeve [claim 18]. Accordingly, Appellants respectfully submit that Hollister clearly fails to disclose any sleeve, as set forth in the claims of the instant invention.

Moreover, Hollister fails to disclose any sheath, let alone a sheath that fits to a non-existent sleeve for establishing a sterile environment for any needle. Indeed, in Fig. 1 of Hollister, the double ended needle assembly 30 to be used with the holder 2 is shown being separated from holder 2. Therefore, there clearly was no sterile environment for needle 28 envisioned for the Hollister device.

There is moreover no disclosure in Hollister that the combination of the sleeve, the base of the double ended needle, and the sheath would establish an environment for the needle that is impervious to bacteria intrusion, as set forth in claims 10 and 18, and illustrated in Fig. 6 of the specification of the instant application.

In view of the all of the elements of the instant invention as set forth in the at issue independent claims that are missing from Hollister, Appellants respectfully submit that the anticipation rejection of claims 1, 10 and 18 of Hollister is not sustainable.

Appellants further respectfully submit that Hollister also fails to disclose any tortuous path as set forth in claims 2, 11 and 19. Nor for that matter does Hollister disclose any interaction between the respective surfaces of the sheath and the sleeve [claim 2], or the sheath, the base and the sleeve [claims 11 and 19] for effecting the tortuous path. There simply is no tortuous path or any interaction between the different surfaces of the elements disclosed in Hollister for effecting a tortuous path. This is clear insofar as there is no need for the Hollister device to establish a sterile environment insofar as needle 28 of the Hollister device is already exposed to the environment. To provide a sterile environment for a needle that is already exposed to the environment of course would be nonsensical. Accordingly,

Appellants respectfully submit that claims 2, 11 and 19 each are likewise not anticipated by Hollister.

Claims 3, 12 and 20 each recite the sleeve being integrally extending from the extension [claim 3] or the neck [claims 12 and 20] of the holder. As shown in Fig. 1, and the other figures of Hollister, there simply is no extension that extends from receptacle end 6. Accordingly, appellants respectfully submit that each of claims 3, 12 and 20 is separately not anticipated by Hollister.

Nor does Hollister disclose any coacting locking portions at the housing or the sleeve/collar as disclosed in claims 6, 15 and 23.

Neither does Hollister disclose any cover that seals the open end of the vacuum tube holder to provide a sterile environment for the space (19) within the vacuum tube holder, as defined in claim 7, 16 and 26.

In sum, it is respectfully submitted that each of claims 1-3, 6-7, 9-12, 15, 18-20, 23-24 and 26 is separately patentable over Hollister, as the limitations recited in those claims, as noted above, are missing from Hollister, either expressly or inherently.

Issue 2

Appellants respectfully submit that each of claims 9, 16 and 24 is patentable over the combination of Hollister and Imbert U.S. patent 5,624,402.

Claims 9, 16 and 24, which depend from independent claims 1, 10 and 18, respectively, each recite means (claim 9) or a tamper seal [claims 16 and 24] on the sheath and the sleeve to provide evidence that the sealed environment of the needle has been compromised. See Fig. 2 of the instant invention specification showing tamper evidence seal 40 on both sleeve 14 and the lower portion of sheath 28.

As discussed above in issue 1, Hollister does not disclose any sleeve or sheath. Imbert, on the other hand, does disclose a frangible label 86. However, label 86, as shown in Fig. 8 of Imbert, is placed on an outer cap 58 and the luer

collar 144 of a syringe 112. The reason that an outer cap, and a corresponding inner cap, is used for the syringe of Imbert is that the combination of inner cap 58 and outer cap 56, best shown in Fig. 1 as the tip cap assembly 54, is used as a plug to the tip 22 of glass syringe 12. The reason that a plug is needed is because the syringe disclosed in Imbert is prefilled with medication, and therefore requires that its tip 22 be plugged to prevent contamination or leakage of the medication stored in the syringe. Luer collar 144 provides the structure to enable the tip cap assembly to be secured to the tip of the syringe. Thus, as disclosed in column 6, lines 42-50, the frangible label 86 is adhesively applied across the interface of the outer cap 58 and the luer collar 144.

Given that Hollister does not disclose any sleeve or sheath, and Imbert likewise fails to disclose any sheath for covering a needle prior to its use, the combination of Hollister and Imbert therefore fails to render as obvious the use of a tamper seal to provide indication that a sterile environment in which a needle resides has been breeched. Indeed, there is no needle disclosed in Imbert, at least not with respect to the use of the frangible label 86 shown in Fig. 8. Accordingly, Appellants respectfully submit that each of claims 8, 16 and 24 is not obvious over the combination of Hollister and Imbert.

In summation, Appellants respectfully submit that the prior art rejections of the at issue claims, as discussed in Issues 1 and 2 above, each are not sustainable. Accordingly, Appellants respectfully request that the examiner's rejections of pending claims 1-3, 5-12, 14-20 and 22-26 be reversed.

Respectfully submitted,

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APPENDIX A

1. (original) Apparatus, comprising:

a holder having one and other ends, said one end having an extension and a sleeve extending from said extension;

a double ended needle having a base mated to said extension of said one end of said holder, one end of said needle extends away from said holder while other end of said needle extends into said holder, said base of said needle being substantially positioned within said sleeve;

a collar mounted about said extension;

a housing pivotally extending from said collar;

a sheath having an open end, said open end having a circumference that enables the sheath to matingly fit to said sleeve to establish an environment sealed against bacteria intrusion for said one end of said needle.

2. (original) Apparatus of claim 1, wherein the surface of the open end of said sheath and the surface of said sleeve that come into contact with each other effect a tortuous path to seal the inside of said sheath against potential bacteria intrusion.

3. (original) Apparatus of claim 1, wherein said sleeve integrally extends from said extension.

4. (withdrawn) Apparatus of claim 1, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said extension and through which the portion of said base of said needle that mates to said extension passes, said sleeve sealingly fitting onto said extension when said base of said needle is mated to said extension.

5. (original) Apparatus of claim 1, wherein said housing further comprises an integral locking means for grasping said one end of said needle when said housing is pivoted to cover said one end of said needle after said sheath has been removed from said sleeve.

6. (previously presented) Apparatus of claim 1, wherein said housing comprises at least one locking portion that coacts with at least another locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said one end of said needle after said sheath has been removed from said sleeve.

7. (original) Apparatus of claim 1, further comprising:
a cover sealing said other end of said holder to provide a sterile environment for the inside of said holder.

8. (original) Apparatus of claim 1, wherein said collar is rotatable about said extension so that said housing is rotatable relative to said one end of said needle.

9. (original) Apparatus of claim 1, further comprising:
means on said sheath and said sleeve to provide evidence that the sealed environment of said one end of said needle has been compromised.

10. (original) Blood drawing device comprising a holder having one and other ends, said one end having a neck to which a sleeve extends, a double ended needle connected to said neck via a base so that one end of said needle extends away from said holder and other end of said needle extends within said holder, a collar having a housing pivotally connected thereto mounted about said neck, a sheath having an open end matingly fitted to said sleeve, wherein said base is positioned substantially within said sleeve and said open end of said sheath is fitted to said sleeve in such a way that said sleeve, said base and said open end of said sheath in combination establish an environment impervious to bacteria intrusion for the space inside said sheath that encloses said one end of said needle.

11. (original) Device of claim 10, wherein the surfaces of said sheath that come into contact with the respective surfaces of said base and said sleeve effect a tortuous path to seal said space inside said sheath that encloses said one end of said needle.

12. (original) Device of claim 10, wherein said sleeve integrally extends from said neck.

13. (withdrawn) Device of claim 10, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said neck sealingly fitted onto said neck when said needle is connected to said neck.

14. (original) Device of claim 10, wherein said housing further comprises an integral locking means for grasping said needle when said housing is pivoted to cover said needle after said sheath has been removed from said sleeve.

15. (original) Device of claim 10, wherein said housing comprises at least one locking portion that coacts with at least an other locking portion at said collar or said

sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said needle after said sheath has been removed from said sleeve.

16. (original) Device of claim 10, further comprising:

a cover sealing said other end of said holder to provide a sterile environment for the inside of said holder; and

a tamper seal on said sheath and sleeve that, when broken, provides evidence that the sealed environment of said needle has been compromised.

17. (original) Device of claim 10, wherein said collar is rotatable about said neck and said housing is rotatable relative to said needle.

18. (original) A needle device comprising a body having a neck to which a needle is connected via a base, a sleeve extending from said neck to enclose said base, a collar having a housing for covering said needle pivotally connected thereto mounted about said neck, a sheath having an open end matingly fitted to said sleeve, said sleeve, said base and said open end of said sheath that mates to said sleeve in combination establish an environment impervious to bacteria intrusion for the space inside said sheath that encloses said needle.

19. (original) Device of claim 18, wherein the surfaces of said sheath that come into contact with the respective surfaces of said base and said sleeve effect a tortuous path to seal said space inside said sheath that encloses said one end of said needle.

20. (original) Device of claim 18, wherein said sleeve integrally extends from said neck.

21. (withdrawn) Device of claim 18, wherein said sleeve comprises a semi-closed end having an opening substantially matching the opening of said neck sealingly fitted onto said neck when said needle is connected to said neck.

22. (original) Device of claim 18, wherein said housing further comprises an integral locking means for grasping said needle when said housing is pivoted to cover said needle after said sheath has been removed from said sleeve.

23. (original) Device of claim 18, wherein said housing comprises at least one locking portion that coacts with at least an other locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said needle after said sheath has been removed from said sleeve.

24. (original) Device of claim 18, further comprising:

a tamper seal on said sheath and sleeve that, when broken, provides evidence that the sealed environment of said needle has been compromised.

25. (original) Device of claim 18, wherein said collar is rotatable about said neck and said housing is rotatable relative to said needle.

26. (original) Device of claim 18, wherein said body comprises a Vacutainer holder having one end wherefrom said neck extends and an other open end sealed with a cover to provide a sterile environment within said holder.

CITATIONS